

Application No. 10/517,362
Response date May 21, 2008
Reply to Office Action of March 28, 2008

Docket No. O-2002.732US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	Docket No.:	O-2002.732US
Henrik H. De Nijs et al.	:		
Serial No:	:	Examiner:	R.A. Houghtling
10/517,362	:		
Filing Date:	:	Group Art Unit:	1617
November 30, 2004	:		
Title:	:	Confirmation No.:	5594
USE OF ETONOGESTREL ESTERS	:		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Office Action dated March 28, 2008 having a shortened statutory one-month period for response which expired on April 28, 2008.

Applicants herein petition for a one-month extension of time. The Commissioner is authorized to charge this fee and any deficiency or credit any excess to Deposit Account No. 50-4205.

The Examiner asserts that the claimed subject matter is drawn to two distinct inventions and has required restriction to one of the following inventions, Group I, claims 32-36 drawn to a pharmaceutical composition comprising a therapeutically effective amount of etonogestrel; and Group II, claims 37-41 drawn to a method for contraception and/or hormone replacement therapy comprising administering to a subject by injection a therapeutically effective amount of etonogestrel; wherein the etonogestrel is contained in an oily medium. The Examiner also asserts that restriction into two groups is required because Groups I and II lack the same or corresponding special technical feature. The Examiner also asserts that special technical features as defined in PCT Rule 13.2 refers to those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The Examiner also asserts that since the common technical feature is the compound etonogestrel, that this element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the reference, Roumen et al., Human Reproduction, Vol. 16, pp.469-475, 2001 and is

also found in claim 32 of the pending application. The Examiner concludes that there is a lack of unity of inventions, and therefore restriction for examination purposes is proper.

Applicants provisionally elect, with traverse, to prosecute the invention Group I, claims 32-36. Applicants expressly reserve the right to file a divisional application directed to the non-elected claims of the application in the event the Examiner's requirement for election becomes final. In addition, Applicants expressly reserve the right to rejoin the claims of the non-elected Group II upon allowance of one or more of the claims of elected Group I.

This election is made with traverse because it is believed that claims 32-36 and 37-41 can be regrouped into a single group for examination. As the Examiner is aware, there are two criteria for a restriction requirement: (A) the inventions must be independent or distinct as claimed; AND (B) there must be a serious burden on the Examiner. "If the search and examination of an entire application can be made without a serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." M.P.E.P. §803.

MPEP §808.02 further indicates with respect to establishing a serious burden that the Examiner must show by appropriate explanation one of the following: A) Separate classification thereof; B) A separate status in the art when they are classifiable together, or C) A different field of search.

With regard to the requirement of establishing a serious burden, the Examiner has not provided any explanation why there would be a serious burden to examine Groups I and II together. In particular, in establishing a serious burden the Examiner has not shown by appropriate explanation: A) Separate classification thereof; B) A separate status in the art when they are classifiable together, or C) A different field of search, as is required by MPEP §808.02. Indeed, the method of contraception and/or hormone therapy of claims 37-41 of Group II require the same etonogestrel undecanoate and/or etonogestrel decanoate and/or etonogestrel dodecanoate as recited in the pharmaceutical composition of claims 32-36 of Group I. As both Groups I and II require the same three compounds, it is submitted that the searches for both Groups I and II would have extensive overlap of art. Since, the Examiner has not provided any explanation whatsoever as to why a serious burden would be established on USPTO resources to search and examine Groups I and II together, and the subject matter of Group I substantially overlaps with the subject matter of Group II, it is respectfully submitted that the Examiner must examine claims 32-41 as a single group.

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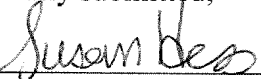
In view of the above, withdrawal of the requirement for restriction is respectfully requested. Applicants retain the right to petition from this requirement under 37 C.F.R. §1.144.

An Action on the merits is respectfully requested.

Dated: May 21, 2008
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Respectfully submitted,

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